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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,384	03/16/2001	Lorenz Studer	11613.0037USWO	5331

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EXAMINER
LOEB, BRONWEN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/17/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,384

Applicant(s)

STUDER ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 Jul 2002 & 30 Sep 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 18-20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 19 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-11, 20, 22, 23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This action is in response to the amendment filed 26 July 2002 in which claims 1, 20, 23 and 24 were amended, claims 14, 15 and 21 were cancelled and new claims 25-27 were presented and in response to the supplemental amendment filed 30 September 2002 in which claim 1 was amended.

Claims 1-11, 18-20 and 22-27 are pending.

Response to Amendment

1. The rejection of claims 14 and 15 under 35 U.S.C. §112, first paragraph for lack of enablement has been withdrawn in view of Applicant's amendment.

The rejection of claims 14 and 15 under 35 U.S.C. §112, second paragraph as being indefinite has been withdrawn in view of Applicant's amendment.

The rejection of claim 21 under 35 U.S.C. §112, first paragraph, for lack of enablement has been withdrawn in view of Applicant's amendment.

The rejection of claims 20-24 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 3 and 7-11 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buc-Caron (Neurobiology of Disease (1995) 2:37-47) has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-4 and 7-11 under 35 U.S.C. §103(a) as being unpatentable over Buc Caron, in view of Studer (Current Protocols in Neuroscience

(1997) Vol. 1, Unit 3.3, pp. 3.3.1-3.3.12; cited in IDS Paper #6) has been withdrawn in view of Applicant's amendment.

2. Claims 1-11, and new claim 25, stand rejected under 35 U.S.C. §112, first paragraph, scope of enablement, for reasons of record and as further discussed below.

Claims 20, 22 and 23 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement for reasons of record and as further discussed below.

3. New grounds of rejection, necessitated by Applicant's amendment, are set forth below.

Response to Arguments

4. With regard to the rejection of claim 1-11 and new claim 25 under 35 U.S.C. §112, first paragraph, scope of enablement, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues the specification enables the full scope of the claims "as it provides considerable guidance to one of skill in the art regarding fetal CNS precursor cells, including a functional description, where they can be found, and when they should be harvested". Applicant states that a precursor cell is defined as "a cell that is capable of differentiating to form a specific cell type, but does not yet express proteins associated with a specific cell type" and that it is within the capability of one of skill in the art to determine if a cell is a precursor cell by determining whether it expresses the proteins of the corresponding differentiated cell type. Applicant further argues that the specification defines "sensitive period" as "the period during which precursor cells can

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be obtained that produce a very large number of a specific differentiated cell type" and that those of skill in the art could readily ascertain from known neural development patterns when fetal CNS cells begin to differentiate into their respective cell types. These arguments are not persuasive. First, Applicant has not provided any objective support (such as journal articles) for their statements regarding what one of skill in the art would know with regard to either precursor cells or a sensitive period. Second, there is no definition in terms of *biochemical* or *molecular features* which would provide guidance for other species to obtain the appropriate precursor cell for proliferation and differentiation in vitro. The definition provided of a precursor cell is a function (capable of differentiating to form a specific cell type) coupled with a negative physical characteristic (it does not express proteins of a specific cell type). There is, however, no guidance regarding a positive physical characteristic that correlates with the capacity to differentiate into a specific cell type (or at least, dopaminergic neuron cells). Thus, the problem is not simply one of assaying protein expression on a cell type but rather, the lack of protein expression coupled with a functional capacity. The desired precursor cells are to be obtained at a "sensitive time", which is also defined only by a function, the capacity to produce a very large number of specific differentiated cell types, and without specifying what "a very large number" is. Thus, one of skill in the art must, for each organism other than rat and human, determine de novo which cells of the fetal CNS are precursor cells that lack specific protein expression as precursors but have the capacity to differentiate into a specific cell type (at least, dopaminergic neuron cells) expressing specific proteins. Furthermore, one must determine de novo the "sensitive

period” by obtaining precursor cells at multiple different time points during fetal development of each organism and subject them to the proliferation and differentiation procedure in order to determine the “sensitive period” for each organism. These determinations are very arduous, time-consuming, trial-and-error undertakings, and thus require undue experimentation for one of skill in the art to make and use the claimed method in a scope commensurate with the scope of the claims. The rejection is maintained.

5. With regard to the rejection of claims 20, 22 and 23 under 35 U.S.C. §112, first paragraph, for lack of enablement, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant has amended claim 20 to recite treating a patient for Parkinson's disease and has argued persuasively that the working example provided in the specification enables the method for treating Parkinson's disease. These claims however remain rejected as they have dependency on the method of claim 1, which is itself not fully enabled.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 25-27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is vague and indefinite in reciting “a sensitive period” which is not a term of art and is defined in the specification as “the period during which precursor cells can be obtained that produce a very large number of a specific differentiated cell type”. This definition is unclear as the phrase “a very large number” is a relative one. Thus the metes and bounds of the claim cannot be determined.

Conclusion

Claims 18, 19 and 24 are allowed. Claims 1-11, 20, 22, 23 and 25-27 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

December 15, 2002



JAMES KETTER
PRIMARY EXAMINER